# DELAWARE HEALTH AND SOCIAL SERVICES

## RESEARCH ABSTRACT

## FOR APPLICATION TO
## THE HUMAN SUBJECTS REVIEW BOARD (HSRB)

***The form below is to be completed for all projects involving research and human subjects within the Department of Health and Social Services, in compliance with DHSS Policy Memo 55.***

***In addition to completion of the form provided here, the researcher will need to submit any proposal prepared for the funding agency to the HSRB.***

***The researcher also needs to sign and submit an Investigator's Agreement, which is available from the HSRB chairperson, and a Certificate of Completion of Training on Human Subjects Protection.***

***Item 20 below relates to review of the project by the Attorney General's Office. This submission is to be handled by the Division Director and should be done prior to submitting the material to the Human Subjects***

***Review Board so that any comments from that Office can be used by the Board in its deliberations. The need for this is to be handled on a case-by-case basis.***

***Projects being done as part of school coursework or in fulfillment of requirements for a college degree must be accompanied by a letter from the researcher's faculty advisor or instructor documenting that all project materials have been reviewed by him/her and that the work is endorsed by that individual.***

***Once the form below is completed and signed by the Researcher and the Division Director, one hard copy original of all signed materials, including the Investigator's Agreement and the Training Certificate, should be sent to: Rosanne Griff-Cabelli, Chairperson, Human Subjects Review Board, Division of Management Services, DHSS, Main Building, Herman Holloway Sr. Campus, 1901 N. DuPont Highway, New Castle, DE 19720. In addition, all project materials should be sent electronically (rosanne.griff-cabelli@state.de.us).***

***If there are any documents not available electronically and for those project documents which are extremely lengthy, then paper copies will need to be distributed to Board members by the researcher (addresses will be supplied). For clarification of these instructions, the HSRB chairperson can be reached at 302-255-9133.***

| **Project Descriptions; check all that apply:** |
|---|
| |
| ☐ Must be HIPAA-compliant; involves protected health information maintained by a 'covered entity' |
| |
| ☐ Meets the criteria for exemption from HIPAA compliance allowed under 45 CFR Sec 164.512 (b)(i): involves protected health information to be used by a public health authority for a public health purpose |
| |
| ☐ Access to protected health information included in this project will require tracking on the part of _____ in order to be able to comply with the HIPAA provision that individuals, upon request, must be given an accounting of certain disclosures of their protected health information |
| |
| ☐ No protected health information requested; does not require HIPAA compliance |

**1.Title of project**

**2.Name, address, agency, e-mail address, and phone number of principal investigator(s) or project manager(s)**

**3.Division whose clients/consumers will serve as research subjects**

**4.Name and phone number of Division contact person for the project**

**5.Role of Divisional staff in the project**

**6.Purpose of project; hypotheses; or research questions (including information to substantiate the scientific merit of the project)**

**7.Subjects or Population to be Studied**

a. **Age, gender(s) and approximate number**

b. **Inclusion/exclusion criteria**

**8.Method(s) of Recruitment, including plan for determining and recording reasons for refusal to participate; attach any information sheets or other documents used in recruitment**

**9.Compensation/Inducements to Participate (describe and give justification):**

**10.(a) If prior informed consent will be sought:**
**Method(s) for ensuring participant understanding of the project and obtaining prior informed consent and HIPAA authorization – if applicable [include copy of form(s) to be used].**

**[Note: any 'contact' phone numbers provided should be local or toll-free. If either option is not available, participants should be advised that they can call 'collect.' In addition, the consent document should include the name and phone number of the DHSS HSRB chairperson as a 'contact' for questions participants may have about their rights as research subjects. If the phone number is not 'local' for the participants, they should be advised that they can call 'collect.']**

**Also, provide the following information, to document method(s) used to maximize participant understanding. Please elaborate on/explain any "no" responses in column two.**

| | |
|---|---|
| **Form(s) have been edited to reduce use of technical terms/jargon** | **yes/no** |
| **Form(s) have been pre-tested by individuals comparable to potential participants** | **yes/no** |
| **Form(s) use subheadings** | **yes/no** |
| **Conceptual density has been minimized** | **yes/no** |
| **Active voice is used as much as possible, instead of passive** | **yes/no** |

| | |
|---|---|
| **Assistance is planned to ascertain participant understanding – such as:**<br>❖ **having participant read form aloud to researcher with the option of asking for clarification as the reading progresses;**<br>❖ **having participant rephrase key aspects of the information in the form, as prompted by the researcher;**<br>❖ **having participant respond to questions designed to elicit understanding after going through the form independently first;**<br>❖ **putting a highlighted statement – right before the signature line – urging the individual to be sure to ask the researcher if he/she has any questions at all about the meaning of anything in the consent or authorization form (and in the case of materials that are <u>mailed</u> to potential participants, such a statement could remind the individual of the phone number to call to reach the researcher)** | **Yes/no.** |
| **Readability score of forms (expressed as a grade level) / scale or methodology used** | |
| | |

**10(b).: If a <u>waiver</u> of prior informed consent is requested: explain why the research could not practicably be conducted without the waiver.**

**10©: If a waiver is requested, will this adversely affect the subjects' rights and welfare? Explain response.**

**11. If applicable, method for dealing with research subjects who choose to withdraw from the project and/or revoke their authorization, to include procedures for ensuring that participants understand these are or can be two separate steps.**

**12 (a).Description of any protected health information (PHI) that is being requested from DHSS files (or the files of its contractor agencies) for this research project, along with the justification for needing such information (in order to comply with the "minimum necessary" rule in the HIPAA regulations)**

**12(b).Explain why the research could not practicably be conducted without access to and use of this PHI.**

**13. Plan to ensure that identifying information will be protected from improper use or disclosure and that privacy and confidentiality of data collected will be maintained [include copy(ies) of the Notice of Privacy Practices for the Covered Entity(ies) which maintain(s) the protected health information to be accessed] .**

**14. Plan for destroying all identifiers at the earliest opportunity consistent with conduct of the research; explain if there is a health or research justification for retaining the identifiers, or if such retention is otherwise required by law.**

**15.Methodology and/or description of project approach, including description of plans for data collection and methods that will be used to analyze data, if applicable (include copies of proposed data collection instruments)**

**16.Costs/Funding**

**a. Cost of project to DHSS**

**b. Funding source(s)**

**c. Source of funding after research or pilot phase, if applicable**

**17.Timeframe**

**a. Target start date**

**b. Completion date**

**18. Are subjects/clients at risk for any negative impact (often referred to as "adverse event") or consequences affecting their physical, psychological, economic or social well being as a result of participation in this project?**

**If yes, delineate the type of risk(s), the probability of occurrence, the anticipated level of severity, and steps to be taken to minimize such consequences.**

**19.Anticipated benefit(s) to subjects or society**

**20.Review by Attorney General's Office, if applicable**

**a. Date sent for review**

## b. Feedback received

| Submitted by: _____ |
|---|
| Signature of Researcher/Title/Date |
| My signature attests to my agreement to carry out this project in accordance with the principles of the Common Rule and the Privacy Rule.<br><br>In addition, I hereby assure that the information I obtain as part of this research (including PHI) will not be reused or disclosed to any other person or entity other than those listed on this form, except for authorized oversight of this project or as required by law. If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entity, I will seek approval from the HSRB. |

| Approved by: _____ |
|---|
| Division Director/Date |
| My signature attests to my understanding of and agreement to any HIPAA-related obligations imposed by this project, including any necessary recordkeeping to be able to account for disclosures as mandated by HIPAA regulations. |

| Approved by: _____ |
|---|
| Chairperson, DHSS HSRB/Date |
| My signature attests to the fact that this project was reviewed and approved by the DHSS Human Subjects Review Board / Privacy Board. |

| Approved by: _____ |
|---|
| Secretary/Date |
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